

CLAIMS

What I claim is:

1. A method for detecting the onset of inspiratory effort ( $T_{\text{onset}}$ ) in a patient on mechanical ventilation, comprising the steps of:
  - (a) monitoring airway pressure, rate of gas flow, and volume of gas flow of the patient;
  - (b) applying a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert the gas flow signal into a gas flow pressure signal;
  - (c) applying a gain factor ( $K_v$ ) to the signal representing volume of gas flow, also to convert the gas volume signal into a gas volume pressure signal;
  - (d) generating a composite pressure signal comprising the sum of airway pressure signal, gas flow pressure signal, and gas volume pressure signal, with all signals having suitably adjusted polarity;
  - (e) adjusting  $K_f$  and  $K_v$  to result in a desired linear trajectory of composite pressure signal baseline in the latter part of the exhalation phase;
  - (f) comparing (i) current composite pressure signal values with selected earlier composite pressure signal values, and/or
    - (ii) current composite pressure signal values with values expected at current time based on extrapolation of composite pressure signal trajectory at specified earlier times, and/or
    - (iii) the current rate of change in the composite pressure signal with a selected earlier rate of change in the composite pressure signal;
  - (g) comparing differences obtained from such comparison(s) made in step (f) with selected threshold values; and
  - (h) identifying  $T_{\text{onset}}$  when at least one of said differences exceeds said threshold values.
2. The method of claim 1 wherein the composite pressure signal incorporates a fourth component, consisting of the square of the rate of gas flow, to which a gain factor ( $K_d$ ) is applied to convert said fourth signal to a pressure signal and where  $K_d$  is also used to adjust the trajectory of composite pressure signal baseline in the latter part of the exhalation phase.

3. The method of claim 2 wherein  $K_{D2}$  is assigned a value corresponding to the  $K_2$  constant of the endotracheal tube in place in the patient.
4. The method of any one of claims 1 to 3 wherein  $K_v$ ,  $K_f$  and/or  $K_{D2}$  are adjusted to result in a specified slope or pattern of composite pressure signal during part or all of the expiratory phase.
5. The method of any one of claims 1 to 4 wherein a default value of  $K_f$  is used while the value of  $K_v$  is adjusted to obtain a desired baseline composite pressure signal trajectory.
6. The method of any one of claims 1 to 4 wherein a default value of  $K_v$  is used while the value of  $K_f$  is adjusted to obtain a desired baseline composite pressure signal trajectory.
7. The method of any one of claims 1 to 4 wherein the  $K_f$  value used is a known or estimated value of respiratory system resistance of the patient.
8. The method of any one of claims 1 to 4 wherein the  $K_v$  value used is a known or estimated value of respiratory system elastance of the patient.
9. The method of any one of claims 1 to 8 wherein current composite pressure signal value is compared with the composite pressure signal value at the most recent point where the composite pressure signal began a new rising phase and  $T_{onset}$  is identified when the calculated difference exceeds a set threshold value.
10. The method of any one of claims 1 to 9 wherein  $T_{onset}$  detection is precluded in the early part of the exhalation phase.
11. The method of any one of claims 1 to 10 wherein composite pressure signal amplitude is monitored through the inspiratory phase, and wherein the end of inspiratory effort ( $T_{end}$ ) is identified from a reduction in composite pressure signal amplitude, or composite pressure signal slope, below a specified value.
12. The method of claim 11 wherein said specified value is a specified fraction of the highest value obtained earlier during said inspiratory phase.
13. The method of claim 11 or 12 wherein  $T_{end}$  detection is precluded in the early part of the inflation phase.
14. The method of any one of claims 11 to 13 wherein signals corresponding to  $T_{end}$  are used to cycle off ventilator cycles.

15. A method for detecting the onset of inspiratory effort ( $T_{\text{onset}}$ ) in a patient on mechanical ventilation, comprising the steps of:

- (a) monitoring airway pressure and rate of gas flow of the patient;
- (b) applying a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert the gas flow signal into a gas flow pressure signal;
- (c) generating a composite pressure signal comprising the sum of airway pressure signal and the gas flow pressure signal, with the two signals having suitably adjusted polarity;
- (d) comparing (i) the current composite pressure signal values with values expected based on extrapolation of composite pressure signal trajectory at specified earlier times, and/or  
(ii) the current rate of change of composite pressure signal with a selected earlier rate of change of composite pressure signal;
- (e) comparing differences obtained from such comparison(s) made in step (d) with selected threshold values; and
- (f) identifying  $T_{\text{onset}}$  when at least one of said differences exceeds said threshold values.

16. The method of claim 15 wherein composite pressure signal incorporates a third component, consisting of the square of the rate of gas flow, to which a gain factor ( $K_d$ ) is applied to convert said third signal to a pressure signal.

17. The method of claim 15 or 16 wherein selected  $K_f$  is known or assumed value of respiratory system resistance.

18. The method of any one of claims 1 to 17 wherein generated signals representing  $T_{\text{onset}}$  are used to trigger ventilator cycles.

19. A method for cycling off the inflation phase of a mechanical ventilator comprising:

measuring the average interval between patient inspiratory efforts in a patient in a suitable number of elapsed breaths ( $T_{\text{TOT}}$ ) with said average being updated at suitable intervals;

identifying onset of current inspiratory effort;

monitoring time from said onset of inspiratory effort; and

generating a signal that causes the ventilator to cycle off when time elapsed since onset of inspiratory effort exceeds a specified fraction of  $T_{TOT}$ .

20. The method of claim 19 wherein the time to generate a signal to cycle off the ventilator is calculated from the trigger time of current ventilator cycle plus a specified fraction of  $T_{TOT}$ .

21. A method for cycling off the inflation phase of a ventilator in pressure support ventilation comprising:

measuring the interval between successive inspiratory efforts in a suitable number of elapsed breaths ( $T_{TOT}$ );

measuring inspiratory flow rate at specified times in those elapsed breaths which triggered ventilator cycles, said specified times corresponding to a specified fraction of the  $T_{TOT}$ , measured from the onset of inspiratory effort of said each breath or from the trigger time of the ventilator;

calculating the average of the flow values obtained at said specified times in said elapsed breaths; and

generating a signal that causes the ventilator to cycle off when inspiratory flow in the current inflation phase decreases below said average flow value.

22. A method for cycling off the inflation phase of a ventilator in which the ventilator is made to cycle off at a time corresponding to the later of a) end of inspiratory effort, as determined by a method of any one of claims 11 to 13, or, b) the time determined from a method of any one of claims 19 to 21.

23. The method of any one of claims 1 to 22 wherein results concerning patient ventilator interaction are displayed, such results including displays of at least one of the composite pressure signal itself,  $T_{onset}$  and  $T_{end}$  markers, and trigger delay, cycling-off errors, patient respiratory rate, number and frequency of ineffective efforts, and frequency and duration of central apneas, desirable duration of inflation phase, and flow at a specified fraction of  $T_{TOT}$  of the patient in the pressure support ventilation mode.

24. A device for detecting the onset of inspiratory effort ( $T_{onset}$ ) in a patient on mechanical ventilation, comprising:

circuitry for measuring airway pressure, rate of gas flow and volume of gas flow of the patient;

amplifier to apply a gain factor ( $K_f$ ) to the signal representing rate of gas flow to convert said signal into a gas flow pressure signal;

amplifier to apply a gain factor ( $K_v$ ) to the signal representing volume of gas flow, to convert said signal into a gas volume pressure signal;

summing amplifier that generates a composite pressure signal comprising the sum of airway pressure signal, the gas flow pressure signal, and the gas volume pressure signal, with all signals having suitably adjusted polarity;

means to permit adjustment of  $K_f$  and  $K_v$  to provide a desired trajectory of composite pressure signal baseline in the latter part of the exhalation phase;

circuitry to direct said composite pressure signal to a  $T_{onset}$  identification circuitry during a suitable period in the expiratory phase, said identification circuitry comprising circuitry to detect a change in trajectory; and

means for generating a signal corresponding to  $T_{onset}$  when measured change in trajectory of composite pressure signal exceeds a specified threshold.

25. The device of claim 24 wherein an additional signal is generated to be summed by summing amplifier, said additional signal being generated by multiplying the flow signal by the absolute value of the flow signal and applying a gain factor ( $K_D$ ) to the resulting squared flow signal using an amplifier and wherein  $K_D$  is also used to adjust the trajectory of composite pressure signal baseline in the latter part of the exhalation phase.

26. The device of claim 25 wherein  $K_D$  is assigned a value corresponding to the  $K_2$  constant of the endotracheal tube in place in the patient.

27. The device of any one of claims 24 to 26 wherein  $K_f$  is fixed at a default value while adjustment of signal trajectory is made using  $K_v$  and/or  $K_D$ .

28. The device of any one of claims 24 to 26 wherein  $K_v$  is fixed at a default value while adjustment of signal trajectory is made using  $K_f$  and/or  $K_D$ .

29. The device of any one of claims 24 to 28 wherein the summing amplifier input related to the volume of gas flow is omitted.

30. The device of any one of claims 24 to 29 including circuitry that precludes  $T_{onset}$  identification during a specified period after the end of ventilator's inflation phase.

31. The device of any one of claims 24 to 30 wherein the  $T_{\text{onset}}$  identification circuitry comprises circuitry to obtain the rate of change in amplitude of the composite pressure signal and to obtain the difference between current said rate of change with said rate of change of the composite pressure signal at a specified earlier time, and to generate a  $T_{\text{onset}}$  signal when said difference exceeds a set threshold value.

32. The device of any one of claims 24 to 31 wherein the  $T_{\text{onset}}$  identification circuitry comprises circuitry to measure the difference between current amplitude of the composite pressure signal and signal amplitude of the composite pressure signal at a specified earlier time, and to generate a  $T_{\text{onset}}$  signal when said difference exceeds a set threshold value.

33. The device of any one of claims 24 to 28 and 30 to 32 wherein  $K_v$  and/or  $K_f$  and/or  $K_{f2}$  are adjusted to produce a horizontal or slightly downward sloping composite pressure signal baseline in the latter part of expiration and the  $T_{\text{onset}}$  identification circuitry comprises circuitry to measure the difference between current amplitude of the composite pressure signal and amplitude of the composite pressure signal at the most recent point where the composite pressure signal began rising, and to generate a  $T_{\text{onset}}$  signal when said difference exceeds a set threshold value.

34. The device of any one of claims 24 to 33 wherein the generated composite pressure signal is gated to circuitry to identify end of inspiratory effort ( $T_{\text{end}}$ ) said circuitry comprising:

circuitry to identify the highest amplitude (peak) of the composite pressure signal reached during the current inspiratory effort;

circuitry to detect when amplitude of the composite pressure signal decreases below a specified value beyond the time at which said peak occurred; and

circuitry to generate a signal corresponding to  $T_{\text{end}}$  when said amplitude of the composite pressure signal decreases below said specified value.

35. The device of claim 34 where said specified value is a specified fraction of peak amplitude of the composite pressure signal.

36. The device of claim 34 or 35 wherein circuitry is provided to preclude detection of  $T_{\text{end}}$  during a specified period following ventilator triggering.

37. The device of any one of claims 24 to 36 wherein signals corresponding to  $T_{\text{onset}}$  are used to trigger ventilator cycles and/or signals corresponding to  $T_{\text{end}}$  are used to cycle off inflation phase of ventilator.

38. A device for estimating a desirable duration of inflation phase of a ventilator, comprising:

    circuitry to identify inspiratory efforts of a patient;

    means to calculate the time difference between patient inspiratory efforts (patient  $T_{\text{TOT}}$ );

    means for displaying a value corresponding to a specified fraction of patient  $T_{\text{TOT}}$ , said specified fraction being a user input or a default value between 0.3 and 0.5.

39. The device of claim 38 where a signal is generated to cycle off the inflation phase of the ventilator when said desirable duration has elapsed after ventilator triggering.

40. The device of claim 38 wherein a signal is generated to cycle off the inflation phase of the ventilator when said desirable duration has elapsed after onset of inspiratory effort in current breaths or after a point intermediate between onset of effort and ventilator triggering.

41. The device of claim 39 or 40 wherein a user input is provided for inputting patient  $T_{\text{TOT}}$  or its reciprocal, patient respiratory rate, and said input is used by the device, in lieu of device-determined patient  $T_{\text{TOT}}$ , to determine desirable duration of inflation phase.

42. A device for determining the desirable inspiratory flow threshold for terminating inflation cycles in the pressure support ventilation mode comprising:

    circuitry for estimating desirable duration of inflation phase of the ventilator;

    means to measure inspiratory flow in recently elapsed breaths after said desirable duration has elapsed from the ventilator's trigger time, or from the onset of inspiratory effort preceding triggered breaths, or from a specified point in between the latter two points; and

    means for displaying the value of said measured flow.

43. The device of claim 42 wherein the value of said measured flow is communicated to cycling mechanism of the ventilator to effect termination of the

inflation phase when said measured flow, or a reasonable approximation thereof, is reached during the inflation phase.

44. The device of any one of claims 24 to 43 wherein values relevant to patient ventilator interaction are calculated and displayed, such values including displays of at least one of the composite pressure signal itself,  $T_{\text{onset}}$  and  $T_{\text{end}}$  markers and displays or outputs indicating trigger delay, cycling-off errors, patient respiratory rate, number and frequency of ineffective efforts, frequency and duration of central apneas, desirable duration of inflation phase, and flow at a specified fraction of patient's  $T_{\text{TOT}}$  in the pressure support ventilation mode.

45. The device of any one of claims 24 to 44 wherein the output of the device is used for closed-loop control of ventilator settings.

46. The device of any one of claims 24 to 45 wherein functions executed by electrical circuitry are executed in whole or in part by digital techniques.